

## PATENT COOPERATION TREATY


REC'D 15 MAR 2005

PCT

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PC23207A	<b>FOR FURTHER ACTION</b>		See Form PCT/PEAA16
International application No. PCT/IB2004/000240	International filing date (day/month/year) 22.01.2004	Priority date (day/month/year) 03.02.2003	
International Patent Classification (IPC) or national classification and IPC A61K7/48			
Applicant WARNER-LAMBERT COMPANY LLC			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 16.02.2004		Date of completion of this report 15.03.2005	
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Voyiazoglou, D Telephone No. +31 70 340-3355	



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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-34 as originally filed

**Claims, Numbers**

1-10 as originally filed

**Drawings, Sheets**

1-6 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	2-9
	No: Claims	1,10
Inventive step (IS)	Yes: Claims	
	No: Claims	1-10
Industrial applicability (IA)	Yes: Claims	1-10
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Re Item V**

Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

Reference is made to the following documents:

D1:US 2002/155075 A1 (COLLINGTON ERIC WILLIAM) 24 October 2002 (2002-10-24)  
cited in the application

D2:US-A-6 132 740 (HU LAN) 17 October 2000 (2000-10-17) cited in the application

D3:US-A-5 824 326 (CROTTY BRIAN ANDREW ET AL) 20 October 1998 (1998-10-20)

**Lack of novelty**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1,10 is not new in the sense of Article 33(2) PCT.

The document D1 discloses resorcinol derivatives as skin lightening agents. A composition is described on column 10, lines 13-20 which comprises N-methylpyrrolidone, propylene glycol and a skin lightening resorcinol derivative. It is mentioned in the present application (page 21, lines 29-31) that a useful co-solvent is N-methylpyrrolidone. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1,10 is not new in the sense of Article 33(2) PC

**Lack of inventive step**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 2-9 does not involve an inventive step in the sense of Article 33(3) PCT.

The document D2 is regarded as being the closest prior art to the subject-matter of claim and discloses cyclopentyl or cyclohexyl derivatives as skin whitening agents.

The subject-matter of claim 2 therefore differs from this known composition in that the carrier is not the same.

The problem to be solved by the present invention may therefore be regarded as to provide an alternative carrier system which would decrease the amount of active agent. The solution proposed in claim 2 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons.

Document D3 provides a composition comprising the same carrier for skin lightening (see Tables II and III).

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The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 9 which therefore is also considered not inventive.  
Dependent claims 2-8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see documents D2, D3 and the corresponding passages cited in the search report.

**Re Item VII**

Certain defects in the international application

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D3 is not mentioned in the description, nor is this document identified therein. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

The technical terms employed in claim 8 (dimethylisorbide instead of dimethylisosorbide) and on several pages (see for example page 21, palmite, stearite etc) are not generally accepted in the art, contrary to the requirements of Rule 10.1(e) PCT.

Claim 10 should refer only to claims 1-9 and not to itself.

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